

REMARKS

Claims 28, 29 and 36 are pending. Claims 28, 29 and 36 are rejected.

Claim Amendments

Claims 28 and 29 have been amended. No new matter was added. Entry of the amendments is respectfully requested.

Information Disclosure Statement

In the returned information disclosure statement (IDS) filed on April 23, 2004, the Examiner crossed out B18, which is a Japanese patent abstract. The Examiner did not sign off reference C22. Applicants believe these references were properly submitted and respectfully request the Examiner to consider them or sign them off.

First Rejection under 35 U.S.C. §102

Claims 28, 29 and 36 are rejected under 35 U.S.C. §102(a) as being anticipated by U.S. Patent No. 6,527,938 to Bales et al. ("Bales").

Claim 28 defines a method for coating an implantable device, which comprises applying a composition onto the implantable device to form a coating. The composition comprises (1) a first block copolymer comprising a block having a glass transition temperature (T_g) below about body temperature and a second block having a T_g or a melting temperature (T_m) above about body temperature, and (2) a material selected from the group consisting of a biobeneficial polymer conjugated with the first block copolymer, a second block copolymer and a combination thereof, the second block copolymer comprises (i) a biobeneficial component and (ii) a component selected from the group consisting of components miscible with the first block copolymer and components insoluble in water.

Bales discloses that microporous coatings for a stent have been based on “bio-compatible polymers (such as poly(styrene-co-isobutylene-co-styrene) (SIBS), and bio-resorbable polymers, such as polyglycolic acid.” The active agent is mixed with the polymeric coating material, and the mixture is placed onto a metallic stent. (See Bales, col. 2, lines 27-33). However, Bales does not teach the **conjugation** of a first polymer and a **biobeneficial** polymer.

In *Phillips v. AWH Corp.*, the Federal Circuit’s *en banc* decision recognized that “[t]he Patent and Trademark Office (“PTO”) determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction ‘in light of the specification as it would be interpreted by one of ordinary skill in the art.’”¹

First, Applicant has defined a **conjugate** as combining one material with one or more materials “by ionic interaction, hydrogen bonding, or covalent bonding.” (See specification, page 12, lines 12-14). Bales does not disclose that the bio-compatible polymer is conjugated to the bio-resorbable polymer. Bales at most teaches a mixture of bio-compatible polymers and bio-resorbable polymers. Thus Bales cannot anticipate claim 28 of the present invention because Bales fails to disclose a biobeneficial polymer **conjugated** with the first block copolymer.

Second, Applicant has defined a **biobeneficial** material as “one which enhances the biocompatibility of a device by being non-fouling, hemocompatible, actively non-thrombogenic, or anti-inflammatory, all without depending on the release of a pharmaceutically active agent.” (See present application, page 2, lines 19-21). Thus, one of skill in the art would not classify polyglycolic acid as a **biobeneficial** polymer in light of Applicant’s specification, which includes an explicit definition of biobeneficial materials. Therefore, Bales cannot anticipate the present

¹ *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005), quoting *In re Am. Acad. Of Sci. Tech. Ctr.*, 367 F.3d 1359, (Fed. Cir. 2004).

invention because it does not disclose the conjugation of a first block copolymer and a **biobeneficial** polymer.

Thus, Bales does not disclose or teach forming a coating using a composition as defined by claim 28, which comprises a block copolymer AND a material selected from the group consisting of a biobeneficial polymer conjugated with the first block copolymer, a second block copolymer and a combination thereof, the second block copolymer comprising (i) a biobeneficial component and (ii) a component selected from the group consisting of components miscible with the first block copolymer and components insoluble in water. Bales therefore cannot anticipate claim 28. Claim 28 is therefore patentably allowable over Bales under 35 U.S.C. §102(a). Claims 29 and 36 depend from claim 28 and are patentably allowable over Bales under 35 U.S.C. §102(a) for at least the same reason. Reconsideration and withdrawal of the rejections are respectfully requested.

Second Rejection under 35 U.S.C. §102

Claims 28, 29 and 36 are rejected under 35 U.S.C. §102(a) as being anticipated by U.S. Patent No. 6,545,097 to Pinchuk et al. ("Pinchuk").

Pinchuk discloses a stent having a coating formed of SIBS. The coating can include a bioactive agent. The Examiner cites DNA as an active agent. The Examiner also cites DNA as "a copolymer containing a biobeneficial component." It is not clear whether the Examiner cites DNA as the second block copolymer as required in claim 28 of the present invention, or as the active agent, as required in dependent claim 29. Either citation fails for the following reasons.

As to the Examiner's citation of DNA as a copolymer, claim 28 of the present invention requires a second **block** copolymer. DNA is not a **block** copolymer. Therefore, claim 28 is not anticipated by Pinchuk. As to DNA being a bioactive agent as required by claim 29, because

claim 28 is patentable and claim 29 depends from claim 28, claim 29 cannot be anticipated by Pinchuk.

Thus, similar to Bales, Pinchuk fails to disclose or teach forming a coating using a composition as defined by claim 28, which comprises a block copolymer AND a material selected from the group consisting of a biobeneficial polymer conjugated with the first block copolymer, a second block copolymer and a combination thereof, the second block copolymer comprising (i) a biobeneficial component and (ii) a component selected from the group consisting of components miscible with the first block copolymer and components insoluble in water. Claim 28 is therefore patentably allowable over Pinchuk under 35 U.S.C. §102(a). Claims 29 and 36 depend from claim 28 and are patentably allowable over Pinchuk under 35 U.S.C. §102(a) for at least the same reason. Reconsideration and withdrawal of the rejections are respectfully requested.

CONCLUSION

Withdrawal of the rejection and allowance of the claims are respectfully requested. **If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment.** If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Robert P. Auerbach', is written over a horizontal line.

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